QSIC (Dan Verba)
QS Regulatory Affairs (Communications)
= 1st point of contact for FDA

Walk, Roger A.

From: Crincoli, Tony + Alicia
Sent: Thursday, February 06, 2003 8:15 AM
To: Walk, Roger A.
Subject: RE: Current draft Best Practices guide and implementation plan for your review and comments - Action required

FDA contacts:
- Consumer
- Combination Products Group (drugs and device combinations) but mainly resp. for coordination within FDA

Thanks, will call you to set up a time

-----Original Message-----
From: Walk, Roger A.
Sent: Tuesday, February 04, 2003 5:13 PM
To: Crincoli, Tony
Cc: Zhang, Mingda (R&D)
Subject: RE: Current draft Best Practices guide and implementation plan for your review and comments - Action required

I look forward to discuss with you and suggest to invite Mingda Zhang as well. We plan to complete the initiative within the next 2-3 months, hand the then-approved implementation plan to the function leaders and then the process becomes an Enhanced Compliance activity.

Actions:
① Tony will send info material
② Involve QSRA into internal communication.
③ We will work together on facing points
④ Alicia checks for FDA standards that may apply to Guide

- Armond + Porter can help Cygnus in contact with Country offices

Regards,
Roger

-----Original Message-----
From: Crincoli, Tony
Sent: Tuesday, February 04, 2003 1:35 PM
To: Walk, Roger A.
Cc: Westra, Dan L.
Subject: RE: Current draft Best Practices guide and implementation plan for your review and comments - Action required

Roger, regarding my most recent voice mail; this morning I provided a tobacco legislation update at the MC and someone asked a question about our product strategy in the absence of regulation and why haven't we communicated that strategy. Once Louis sent me the attached updated guide and action register I was able to better understand the current status and next steps. When you have a chance I would still like to speak with you about the roll out plan including communication. If you need help in that area let me know. Talk to you soon.

-----Original Message-----
From: Watts, E.L.
Sent: Tuesday, February 04, 2003 1:02 PM
To: Crincoli, Tony
Subject: FW: Current draft Best Practices guide and implementation plan for your review and comments - Action required

Tony:

In response to your voicemail, the document is still in discussion draft. I'm forwarding you the latest draft which should have included as appropriate your comments and Walt's.

I'm no longer working with the team since our reorg; but Sainta still represents QSIC on the team.

Louis

-----Original Message-----
From: Zhang, Mingda (R&D)
Sent: Wednesday, January 29, 2003 9:25 PM
To: Desel, Paula; Garguilo, Thomas M.; Haywood, Sainta; Jupe, Richard; McCormick, Brendan J.; Osborne, Kevin (PMMC Legal); Patskan, George J.; Walk, Roger A.; Wrenn, Sue; Newman, Ken A.; 'Robert Conley'
Cc: Lenling, Amy; Watts, E.L.
Subject: Current draft Best Practices guide and implementation plan for your review and comments - Action required

Dear All,

As mentioned in the meeting invitation I sent on Jan. 17, attached are the current draft Best Practices guide and implementation plan for your review and comments before the BPF Team meeting on Feb. 5.

Crincoli

- The draft BP guide has undergone extensive revision and incorporated many comments/suggestions on the earlier drafts I have received, e.g.:

    - New conventional products and modifications to existing products are now covered by the guide in addition to PREPs and a separate flow chart has been added for conventional cigarettes.
    - Modules on assessment and requirements for claims have been combined into one to both improve the flow of the guide and reduce repetitions.
    - Reference to other relevant guidelines, especially those commonly accepted in toxicological and clinical studies, has been added.
    - The document has been tightened to reduce repetitiveness and achieve a more consistent use of terminology.

Due the extensiveness of the revisions I have attached a "clean" draft without any revision history to make the document easier to read. Please carefully review the attached draft before the team meeting next week as we would like to review and, as much as possible, finalize the guide during the meeting. I would like to draw your attentions to topics that need additional discussion/clarification among the team, which I have highlighted in blue. (The BP elements are highlighted in yellow as in the previous drafts.) Please send your comments to me before the meeting if feasible, which should improve the efficiency of the discussion during the meeting.

- You will notice that there are still some gaps in the attached draft BP implementation plan, which currently reflects my assessment and proposal. I view it as a starting point to stimulate inputs from your respective expertise and functions. That will be essential for completing the implementation plan. Please review the draft contents before the team meeting for all entries, especially those most closely related to your function and those with your name under "Accountability". Please send your comments to me either ahead of the team meeting (preferred) or bring them to the meeting.

We have made tremendous progress on both drafts and I thank you all for your contributions to the progress. I have been informed by Amy and Louis that their responsibilities had recently changed and they would not be participating in future team activities. Let us take this opportunity to than them both for their contributions to this team.

Best regards,

Mingda << File: BP guide draft 030129 clean.doc >> << File: BPF implementation 2003-01-29.doc >>